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EXAMINER

GLASS, RUSSELL S

ART UNIT PAPER NUMBER

3626

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,389

Applicant(s)

HODGES, VANNIE KAY

Examiner

Russell S. Glass

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/10/01.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/10/01.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Requirement for Information Under 37 C.F.R. 1.105

1. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.
2. The information is required to identify products and/or methods embodying the disclosed subject matter for grouping, ranking and associating patent information. The Examiner, upon conducting a search for prior art, discovered several published documents related generally to Applicants' invention and in particular to the Child and Adolescent Functional Assessment Scale (CAFAS).

The published documents are as follows:

Kay Hodges, Child and Adolescent Functional Assessment Scale (CAFAS), *The Use of Psychological Testing for Treatment Planning and Outcome Assessment*, 2nd ed, pp.631-634 (1999).

Kay Hodges, *Child and Adolescent Functional Assessment Scale*, (1990, 1994 revision).

Kay Hodges, A. Doucette-Gates & Q. Liao, *The Relationship Between The Child And Adolescent Functional Assessment Scale (CAFAS) And Indicators Of Functioning*, *Journal of Child and Family Studies*, 8(1), pp. 109-122 (1999).

Kay Hodges and M.M. Wong, *Psychometric Characteristics Of A Multidimensional Measure To Assess Impairment: The Child And Adolescent Functional Scale*, Journal of Child and Family Studies, 5(4), pp. 445-467 (1996).

Kay Hodges and M.M.Wong, Use of the child and adolescent functional assessment scale to predict service utilization and cost, Journal of Mental health Administration, 24(3), pp. 278-290 (1997).

Kay Hodges, M. Wong & M. Latessa, *Use Of The Child And Adolescent Functional Assessment Scale (CAFAS) As An Outcome Measure In Clinical Settings*, Journal of behavioral Health Services & Research, 25(3), pp. 326-337 (1998).

Each of the cited documents appear to have been published more than a year before the Applicant's filing date.

In response to this requirement please provide any known books, publications, brochures, manuals, press releases, research conference proceedings, or any other documents that describe grouping, ranking and associating patient information that is described by the aforementioned documents, and specifically what product or service was marketed or used before December 10, 2000, that was the subject of the article disclosures.

3. The fee and certification requirements of 37 C.F.R. 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 C.F.R. 1.105 that are included in the applicants first complete communication responding to this requirement. Any

supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 C.F.R. 1.105 are subject to the fee and certification requirements of 37 C.F.R. 1.97.

4. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicants disclosure.

5. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained will be accepted as a complete response to the requirement for that item.

6. This requirement is subject to the provisions of 37 C.F.R., sections 1.134, 1.135 and 1.136 and has a shortened statutory period of 2 months. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Claim Objections

7. Claims 14 is objected to because of the following informalities: The claim appears to incorrectly depend upon claim 10 instead of claim 11. If claim 14 were to depend upon claim 10, the scope of the claim would span two statutory classes of invention and would be rejected on that basis. For the purpose of examination, claim 14 is deemed to depend from claim 11, not claim 10.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by McLeod, (U.S. 6,053,866).**

9. As per claim 1, McLeod discloses a method for grouping patients comprising the steps of:

1) analyzing the patient and reaching an evaluation in each of several scales, (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58) (disclosing establishing a preliminary disorder indication by analyzing patient data, assigning a value based on scores of separate question sets related to different psychiatric disorders, and

facilitating a diagnosis of a condition based on the sum of the values of the set, each set considered to be one of several scales);

2) grouping an analyzed patient into one of several groups based upon an evaluation of the rankings in the scales, and utilizing a hierarchy for the scales to perform the grouping, (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58) (disclosing establishing a preliminary disorder indication by analyzing patient data, assigning a value based on scores of separate question sets related to different psychiatric disorders, and facilitating a diagnosis of a condition based on the sum of the values of the set, each diagnosis considered to be one of several groups, and the series of sets is considered to be a hierarchy).

10. As per claim 2, McLeod discloses a method as set forth in claim 1, wherein the grouping of step 2 occurs by evaluating the rankings in a fashion such that if a particular scale is associated with a particularly severe ranking, then a grouping is made based upon the severe ranking, (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58) (disclosing establishing a preliminary disorder indication by analyzing patient data, assigning a value based on scores of separate question sets related to different psychiatric disorders, and facilitating a diagnosis of a condition based on the sum of the values of the set, the sum being indicative of a diagnosis, equivalent to a particularly severe ranking, if falling outside of a numerical range established from a baseline value).

11. As per claim 3, McLeod discloses a method, wherein a scale related to the ability

Art Unit: 3626

to think is utilized as the first scale to be evaluated, and if substantial problems are determined with regard to the thinking scale, then the patient is categorized with a group associated with thinking problems, (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58) (disclosing a list of psychiatric disorders considered to include thinking problems).

12. As per claim 4, McLeod discloses a method wherein results of the thinking scale are not high, the next scale evaluated is a substance use scale, and if the substance use scale has a particularly high ranking, then the patient is grouped into a substance use group, (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58) (disclosing a list of psychiatric disorders considered to include substance abuse problems).

13. As per claim 5, McLeod discloses a method, wherein once a particular group has been identified for a patient, questions are asked with regard to the family or home of the patient to identify a recommended intensity of treatment, (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58; col. 6, line 54-col. 26, line 41) (disclosing a questions considered to illicit information regarding the home or family of a patient).

14. As per claim 6, McLeod discloses tool for ranking patients comprising: a flowchart for evaluating scores in several scales, said scales at least including a scale relating to a patient's ability to think, a patient's substance use history, and a patient's self-harmful behavior, said flowchart applying the scales in a hierarchy, and moving the patient into being placed in any one of a plurality of groups while moving through said

hierarchy of scales, if a particular scale is associated with a ranking above a particular value, (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58) (disclosing establishing a preliminary disorder indication by analyzing patient data, assigning a value based on scores of separate question sets related to different psychiatric disorders considered to include a patient's ability to think, a patient's substance use history, and a patient's self-harmful behavior, and facilitating a diagnosis of a condition based on the sum of the values of the set, the sum being indicative of a diagnosis, equivalent to a particularly severe ranking, if falling outside of a numerical range established from a baseline value).

15. As per claim 7, McLeod discloses a tool as recited in claim 6, wherein said flowchart is incorporated into a software program in a computer, (McLeod, Abstract; Figure; col. 5, lines 26-58).

16. As per claim 8, McLeod discloses a tool as recited in claim 6, wherein said flowchart is incorporated into paper form, (McLeod, Abstract; Figure; col. 5, lines 26-58).

17. As per claim 9, McLeod discloses a tool as recited in claim 6, wherein additional questions are asked with regard to the family or home for the particular patient, based upon the identified group, and recommendations are made, in part, based upon the family or home of the patient, (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58; col. 6, line 54-col. 26, line 41) (disclosing a questions considered to illicit information

Art Unit: 3626

regarding the home or family of a patient for the purpose of facilitating a diagnosis and addressing patient concerns that are considered to include recommendations).

18. As per claim 10, McLeod discloses a tool as recited in claim 6, wherein once a group has been identified, further questions with regard to the patient's environment are asked to identify recommended care (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58; col. 6, line 54-col. 26, line 41) (disclosing further questioning considered to illicit information regarding the patient's environment).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. **Claims 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by McLeod, (U.S. 6,053,866) in view of Kay Hodges and M.M. Wong, *Use Of The Child And Functional Assessment Scale To Predict Service Utilization And Cost*, Journal of Mental Health Administration, 1997 Summer; 24 (3), p. 278-90 (1997) (hereinafter "Hodges").**

20. As per claim 11, McLeod discloses a method of associating patients with a particular group comprising the steps of:

1) performing an evaluation on a patient to identify scores in at least the thinking scale, the substance use scale and the self-harmful behavior scale,;

2) evaluating the identified scores through a flowchart that asks whether the thinking scale is above a particular value, and if said thinking scale is above said particular value grouping the patient into a thinking tier, and if the thinking scale is below a particular value, next asking whether the substance use score is above a particular value;

3) if the substance use score is above a particular value, grouping the patient into a substance use grouping; and

4) if the substance use score is below a particular value, next asking whether the self-harmful score is above a particular value, and grouping the patient into a self-harmful group, if the self-harmful group score is above a particular value, (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58; col. 6, line 54-col. 26, line 41) (disclosing establishing a preliminary disorder indication by analyzing patient data, assigning a value based on scores of separate question sets related to different psychiatric disorders considered to include a patient's ability to think, a patient's substance use history, and a patient's self-harmful behavior, and facilitating a diagnosis of a condition based on the sum of the values of the set, the sum being indicative of a diagnosis,

Art Unit: 3626

equivalent to a particularly severe ranking, if falling outside of a numerical range established from a baseline value).

McLeod fails to disclose presenting a CAFAS evaluation, but such an evaluation is well-known in the art as evidenced by Hodges, (Hodges, Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the CAFAS multidimensional impairment evaluation into the psychiatric diagnosis system and method disclosed by McLeod. The motivation would have been to predict service utilization and cost of care, (McLeod, Abstract).

21. As per claim 12, McLeod discloses a method as set forth in claim 11, wherein if a mood/emotion score is also above a particular value, grouping the patient into the self-harm group, (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58; col. 6, line 54-col. 26, line 41) (disclosing establishing a preliminary disorder indication by analyzing patient data, assigning a value based on scores of separate question sets related to different psychiatric disorders considered to include a patient's self-harmful behavior and information related to mood/emotion, and facilitating a diagnosis of a condition based on the sum of the values of the set, the sum being indicative of a diagnosis, equivalent to a particularly severe ranking, if falling outside of a numerical range established from a baseline value).

The statement of obviousness and motivation to combine McLeod and Hodges is as provided in the rejection of claim 11 and incorporated herein by reference.

Art Unit: 3626

22. As per claim 13, McLeod discloses a method as set forth in claim 11, wherein if both self-harmful and mood/emotion are below a particular value, next evaluating the patient's community score, and if the community score is above a particular value, grouping the patient into an uncomplicated delinquent group, (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58; col. 6, line 54-col. 26, line 41) (disclosing establishing a preliminary disorder indication by analyzing patient data, assigning a value based on scores of separate question sets related to different psychiatric disorders considered to include a patient's self-harmful behavior, information related to mood/emotion, and information related to a patients community; and then facilitating a diagnosis of a condition based on the sum of the values of the set, the sum being indicative of a diagnosis, equivalent to a particularly severe ranking, if falling outside of a numerical range established from a baseline value).

The statement of obviousness and motivation to combine McLeod and Hodges is as provided in the rejection of claim 11 and incorporated herein by reference.

23. As per claim 14, McLeod discloses a method as set forth in claim 10, wherein once a particular group has been identified for a patient, questions are asked with regard to the family or home of the patient to identify a recommended intensity of treatment, (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58; col. 6, line 54-col. 26, line 41) (McLeod, Abstract; Figure; col. 1, line 58-col. 5, line 58; col. 6, line 54-col. 26, line 41) (disclosing a questions considered to illicit information regarding the home or family of a patient for the purpose of facilitating a diagnosis and addressing patient

concerns that are considered to include recommendations related to intensity of treatment).

The statement of obviousness and motivation to combine McLeod and Hodges is as provided in the rejection of claim 11 and incorporated herein by reference.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure is as follows: Iliff, (U.S. 6,071,236); Kaneko, (U.S. 2003/0028084); Teitelbaum, (U.S. 6,607,482); Darby et al., (U.S. 2005/0143630).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell S. Glass whose telephone number is 571-272-3132. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 3626

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